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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/523,357

09/01/2005

Mickie Bhatia

BP 10188-18

8360

23579 7590 03/07/2008

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EXAMINER

DAVIS, RUTH A

ART UNIT

PAPER NUMBER

1651

MAIL DATE

DELIVERY MODE

03/07/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/523,357	Applicant(s) BHATIA, MICKIE	
	Examiner Ruth A. Davis	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29 and 33-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 29,33-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election of group III, claims 29 and 33 - 41 in the reply filed on December 5, 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1 – 28 and 30 – 32 are canceled; claim 41 is added; claims 29 and 33 – 41 are pending and have been considered on the merits.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 29 and 33 – 41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The instant claims are drawn to a method for treating and preventing pancreatic damage, diabetes and hyperglycemia. However the specification fails to enable one in the art to practice the method for preventing any of the claimed conditions. Prevention of a disease or condition

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requires a significant showing that the disease or condition is actually prevented. The instant conditions are known in the art to be manageable with medications, however the art does not recognize the instant conditions as preventable. Moreover, the specification fails to fully enable one in the art to practice the claimed method of preventing the instant conditions without undue burden of experimentation.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 29 and 33 – 41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 29 and its dependents are drawn to a method for treating/preventing pancreatic damage, however are rendered vague and indefinite for reciting “an effective amount” because it is unclear if the “effective amount” is the same for both treating and preventing as the amounts are not clearly defined by the specification.

Claims 37 and 41 are rendered vague and indefinite because it is unclear if the claims intend the method to further treat diabetes and hyperglycemia, or rather diabetes and hyperglycemia, as the independent claim is drawn to treating pancreatic damage. For purposes of examination the claims have been interpreted as treating pancreatic damage caused by diabetes/hyperglycemia.

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Claim 38 is rendered indefinite for reciting “insulin dependent Type II diabetes”, as it is unclear if the claim intends to recite “non-insulin dependent Type II diabetes” or “insulin dependent Type I diabetes”.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 29, 33 – 34, 36 – 39 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Habner et al. (US 2003/0082155).

Habner teaches methods for treating type I diabetes (abstract) wherein c-kit positive cells are administered (0016). The cells are administered to human patients and may be obtained from a human donor (p.2).

Habner does not specifically teach the method for treating/preventing pancreatic damage or hyperglycemia, however the claims are drawn to preventing the instant conditions in an animal in need. Since it is known that pancreatic damage and hyperglycemia may occur in patients with diabetes, the reference teaches the limitations.

Furthermore, while the reference does not teach the cells are derived from the claimed sources, these limitations are considered product by process type limitations. The patentability of a product does not depend on its method of production. If the claimed product is the same or

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obvious from a product in the prior art (i.e. the product disclosed in the cited reference), the claim is unpatentable even though the reference product was made by a different process. When the prior art discloses a product which reasonably appears to be identical with or slightly different than the claimed product-by-process, rejections under 35 U.S.C 102 and/or 35 U.S.C 103 are proper. (MPEP 2113)

8. Claims 29, 33 - 35, 37 - 38 and 40 - 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ikehara et al. (Proc. Natl. Acad. Sci, 1985).

Ikehara teaches administering bone marrow (containing cells with the claimed markers and mononuclear lymphocytes) to treat type I diabetes (p.7743).

The reference does not specifically teach the method for treating/preventing pancreatic damage or hyperglycemia, however the claims are drawn to preventing the instant conditions in an animal in need. Since it is known that pancreatic damage and hyperglycemia may occur in patients with diabetes, the reference teaches the limitations.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 571-272-0915. The examiner can normally be reached on M-F 7:00 -3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ruth A. Davis/
Primary Examiner, Art Unit 1651

February 28, 2008